

2013-5118

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**United States Court of Appeals  
for the Federal Circuit**

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ILYA DOBRYDNEV,

*Petitioner-Appellee,*

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

*Respondent-Appellant.*

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*Appeal from the United States Court of Federal Claims  
in No. 04-VV-1593, Judge Susan G. Braden*

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**OPENING BRIEF FOR APPELLEE**

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# CERTIFICATE OF INTEREST

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## **STATEMENT OF THE ISSUE**

Was the United States Court of Federal Claims correct in finding that the rulings by the special master in twice denying entitlement to the Petitioner were arbitrary, capricious, an abuse of discretion, and not in accordance with law?

## **STATEMENT OF THE CASE**

### **INITIAL PROCEEDINGS**

Eight years had passed when the final damages portion of the proceedings in this case took place and 11 years had passed since Ilya Dobrydnev had received the hepatitis B vaccination he did not need. The damages hearings held by Special Master Moran following the Final Order granting entitlement issued by the United States Court of Federal Court Claims (1 App. 115) included an August 20, 2012, in-person appearance by Ilya before Special Master Moran in Norfolk, VA., and an October 25, 2012, in-person appearance in Newark, N.J., by Dr. Gudrun Lange a Clinical Neuropsychologist. 4 App. 44-71.

The testimony in these two hearings revealed that at that time, 2012, Ilya was permanently crippled with the neurocognitive impairments of Chronic Fatigue Syndrome. He was easily fatigued, had other physical symptoms such as vestibular neuritis, profound sleep disturbances, and orthostatic intolerance. He also suffered from a debilitating memory, a severe lack of concentration, and attention deficit such that he could not and would not ever be able to live independently or be able to earn a reasonable living in a competitive work environment. Adding insult to his injury, Ilya was intelligent enough to understand his biological imprisonment. 4 App. 271-300.

From these concluding proceedings and other evidence, Special Master Moran, responding to the directions of the United States Court of Federal Claims, issued the final order for monetary relief to Ilya which included a lifetime annuity to aid him for the rest of his life. 1 App 166. From this Order, the Secretary of Health & Human Services (hereafter “government”) appealed. 1 App 167.

This case began on October 24, 2004, when the parents of the petitioner, then a minor, (hereinafter referred to collectively as Petitioner or Ilya) filed a Petition for compensation (1 App. 22). After all of the initial pleadings, reports, and other exhibits had been filed, the first special master, Special Master John F. Edwards, conducted a two-day hearing beginning on June 25, 2007, in Portsmouth, VA. 4 App. 95. Before the beginning of the hearing, counsel for petitioner requested that they be allowed to call their two expert medical witnesses (Dr. David Bell and Dr. James Oleske) to testify as their first witnesses. This request was denied. The special master declared that he wished the mother of the injured child to testify first.

On the first day, due to prolonged cross-examination of the mother, only Dr. Fink and Dr. Bell could be reached. Dr. Oleske began his testimony on the second day. At the conclusion of his testimony, the special master expressed his appreciation to the doctor for remaining while the earlier testimony took place stating, "...I will excuse you as a witness. I do appreciate your patience in



remaining in Court for another day. I know that disrupted your schedule,...” 4 App. 317. This ordinary and professional courteous exchange between Special Master Edwards and Dr. Oleske is noted because it became a part of a later capricious act by the second special master, Special Master Moran.

During the petitioner's portion of the hearing, Yuliya Dobryднеva, Ilya’s mother, an American citizen, but a Russian immigrant with advanced medical education, (1 App. 93) described her young son as a gifted, active boy with an ordinary, childhood medical history until January 2001, when he was infected with mononucleosis, an infection due to the Epstein-Barr virus (EBV). His mononucleosis was resolved by the spring and certainly by the summer of 2001 and the EBV (virus) became dormant or convalescent. During this period, his regular family pediatrician was Dr. Robert Fink.

On November 5, 2001, he was given a hepatitis B vaccination at his school. This was unfortunate because it was a fourth, and therefore, unnecessary vaccination since he had already been immunized in 1992 and 1993 with the usual three shots. Immediately after receiving the November 5, 2001, vaccination he fell acutely ill with malaise, fever, sore throat, swelling in his lymph nodes and marked pallor. He was out of school for a few days but then began thereafter to suffer periodic symptoms of some ailing process. 4 App. 98-133.

On November 30, 2001, Ilya fell violently ill with severe dizziness and nausea. His parents rushed him by ambulance to the hospital where he was diagnosed with vestibular neuritis. The neuritis did not quickly or normally resolve and the symptoms of weakness, vertigo, and fatigue continued. This required him to be bedridden, need constant care, and require homebound school instruction, which were provided through the services of the Norfolk public school system.

He was treated by Dr. Robert Fink, his regular pediatrician, who, in search of answers to Ilya's ailments referred him to numerous specialists who, in turn, offered varying, but unsuccessful diagnoses. 1 App. 78-83.

In March 2002, he was taken to Dr. Mitchell, an infectious disease specialist who expressed the possibility of a "behavioral psychological component contributing to this continued fatigue and possibly school avoidance", but then also noted that "Chronic Fatigue Syndrome itself may be considered in this child". 1 App. 65, 82.

His medical problems continued as his family was desperately seeking answers to why their child was sick and how he could be cured. By April 2002, Dr. Fink considered that he might be suffering from Chronic Fatigue stating, "[p]ossible chronic fatigue secondary to chronic EBV or HSV, though doubt."

2 App. 195. In later testimony, he explained that his reference to “though doubt” was that he doubted that the illness was related to EBV or HSV. 4 App. 301-302.

By the very nature of the disease, a diagnosis of Chronic Fatigue Syndrome cannot be made until four of the defined symptoms persist for six months. While the disease, Chronic Fatigue Syndrome, is a real and recognized neurological disorder characterized by loss of short-term memory and persistent fatigue, many factors define the diagnosis such as headaches, sore throat, malaise, muscle weakness, and swollen or atypical lymph nodes. These symptoms, which occurred during the six months after the vaccination were stated by Dr. Bell, Dr. Oleske, Dr. Parker, and summarized in the opinion and Order by the Court of Federal Claims on 7/30/10. 1 App. 83-84. Dr. David Bell, who performed a lengthy physical examination of Ilya when Ilya was 13 years old, filed subsequent reports in addition to his 2007 and 2010 testimony where he also recorded the symptoms in detail. 2 App. 237-248.

After Dr. Bell’s examination of Ilya, Dr. Fink sought his expertise in treating Ilya. Dr. Bell provided a plan for treatment, which by the nature of that service, he became a treating physician as well as an expert witness, a fact not addressed by the special master. 4 App. 72

Even with these documented symptoms, neither of the two government experts, Dr. Alan I. Brenner and Dr. Raoul L. Wientzen, Jr., made a diagnosis of

Chronic Fatigue Syndrome. In addition, the special master in his first opinion issued on 3/12/10 (1 App. 49-76) nine years after the vaccination, would not acknowledge a diagnosis of Chronic Fatigue Syndrome. 1 App. 75.

The details of Petitioner's medical history as recited by the special master were essentially the same as the medical history detailed by the rulings of the United States Court of Federal Claims except for a few key areas. 1 App 77-95. These key areas included the special master's rejection of the testimony of Ilya's mother and the notes in her diary, the failure to mention the affidavit of Ilya's grandmother, and ignoring the detailed history taken by Dr. Bell when he personally examined the petitioner. In addition, the special master failed to acknowledge the statement of Dr. Fink (Fink's Letter). 2 App. 364-367. The special master's obsession with the mother's testimony and his failure to address her level of medical knowledge was a major point which drew the attention and criticism by the Federal Court of Claims in petitioner's appeal to that Court. 1 App. 93.

The attack on the mother did not go unnoticed by Dr. Oleske, the highly credentialed doctor, who was recognized for his expertise in Chronic Fatigue Syndrome by the Department of Health and Human Services. During that first day of the hearing, most of which was occupied with the harsh and accusatorial cross-examination of Ilya's mother, by the Department of Justice attorney. The

atmosphere resonating in the hearing room was so vitriolic that Dr. Oleske at the conclusion of his testimony on the second day spoke out angrily and spontaneously:

I thought our job was to find out, as best we can tell, was it possible that this child was hurt by this vaccine, and if so he deserves to be compensated and the family. Not whether the mother was a good or bad person or that it was made up or something like that. This is not a tort case, yet I'm finding out that's what happened yesterday, and I'm disappointed in what I've seen happen here. To me, the whole purpose of the immunization compensation was to make sure that the wonderful public health benefit of immunizations, which we know are going to adversely affect some children, we can still reliably, comfortably, and ethically recommend that we put children at risk of those rare adverse events because if something happens we will compensate the families for that and that child and take care of that... It seems to me that the arguments we should be having right now are just what we're having now. Was it the vaccine? The timing of it? All those legitimate questions. All I heard yesterday, though—and I'm sorry to be angry—was not that, was a discrediting of the history based on an attack of a mother who is concerned about her child. To me, that frustrates what the immunization compensation laws are about. Not the Grand [Special] Master, but I'm looking over at you two. I'm sorry about that. I shouldn't get so angry, and I didn't want to do this.

THE COURT: I appreciate your anger, Doctor, and that's something that many folks do express. I think each of us in the room has different roles. 4 App. 150.

## MEDICAL EXPERTS

Both parties offered two medical experts. The petitioner offered Dr. David S. Bell and Dr. James M. Oleske

Dr. David Bell is a Board certified pediatrician, and author of over 35 papers in the field of the prognosis and diagnosis of Chronic Fatigue Syndrome in children. For 3 years, 2003 to 2006, Dr. Bell had been the Chairman of the

Chronic Fatigue Advisory Committee to Department of Health and Human Services, the respondent in this case. 2 App. 248. He testified that he had reviewed the petitioner's medical records and had traveled to Norfolk and performed a careful and detailed physical examination of the petitioner as well as an interview of the family members. He testified that the petitioner suffered from Chronic Fatigue Syndrome and that based upon the medical history he took and the physical examination he made, the petitioner developed Chronic Fatigue Syndrome as a result of the hepatitis B vaccination. His opinion was summarized by the special master at 1 App 83.

The special master also reviewed the report and testimony of Dr. James Oleske, a board certified pediatrician who is also board certified in allergy immunology and pediatric infectious disease. He has had two diagnostic laboratory immunology boards. At the time of his appearance, he was supervising an immunology laboratory, had written over 200 peer reviewed publications in the fields of allergy, immunology, and infectious disease.

Perhaps more to the point of this case, he was actively researching Chronic Fatigue Syndrome in children and adolescents. He had treated over 1,000 patients with chronic fatigue-like syndromes and for five years had been actively participating in a Center for Disease Control study group which was responsible for adverse reactions to immunizations and, like Dr. Bell, was also elected as the

Chairman of the Chronic Fatigue Syndrome Advisory Committee to the Department of Health and Human Services. 2 App. 278. These are among his many other credentials. A summary of his opinion was included in the special master's March 30, 2010, ruling 1 App 84. In spite of the testimony of the treating physician and these two physicians who were selected to the advisory committee for the respondent, the special master refused to acknowledge that the petitioner even had Chronic Fatigue Syndrome.

Following their testimony and the departure of Dr. Bell and Dr. Oleske from the hearing in Portsmouth, VA., the government called their expert witnesses Dr. Alan I. Brenner and Dr. Raoul L. Wientzen, Jr.

Dr. Brenner was board-certified in internal medicine and rheumatology. He was qualified before the special master as an expert in rheumatology. Since 1974, he had seen thousands of patients with Chronic Fatigue Syndrome. He was a founding fellow of the American College of Rheumatology, a member of the American College of Physicians and a member of the New York Academy of Sciences. Since June of 2004, the Southboro Medical Group had employed him where he is the Chief Rheumatologist. 2 App. 355

Dr. Brenner's medical writings have been about anthrax vaccines and he has been a part of the Anthrax Vaccine Expert Committee.

Dr. Brenner testified that there were no studies suggesting a link between a hepatitis B vaccine and Chronic Fatigue Syndrome. He opined that the hepatitis B vaccine was an unlikely cause of a cytokine cascade, as suggested by Dr. Oleske, because the vaccine was not designed to create a strong immune response and that Chronic Fatigue Syndrome was predominantly caused by a viral infection. He believed that EBV would be the primary suspect in this case.

However, as viewed by Special Masters Edwards hearing the testimony, Dr. Brenner's testimony in this case was limited; that is, his role as an expert witness was solely to express the general opinion that “there is [no] medical evidence that hepatitis B vaccine causes chronic fatigue syndrome.” 4 App. 152. Dr. Brenner expressed no opinion about whether Ilya had Chronic Fatigue Syndrome at all. As Special Master Edwards stated during the June 26, 2007 hearing:

...Dr. Brenner is here simply as I understand it from Respondent's statement to present an opinion that hepatitis B does not cause CFS. And in fact, I don't think Dr. Brenner has opined about what Ilya's condition today represents. Dr. Brenner is here for a general opinion. 4 App. 152.

Dr. Brenner's testimony was that he was unaware of articles supporting the medical theory that hepatitis B vaccinations could trigger Chronic Fatigue Syndrome. The articles placed in the record by petitioner contradicted this. The United States Court of Federal Claims in the 5/9/11 decision discussed these articles with approval. 1 App 129.



The second expert called by the government was Dr. Raoul Wientzen, an Associate Dean and Vice Chairman for the Department of Pediatrics at Georgetown Medical School and a member of the Pediatric Infectious Disease Society. In addition to his work at Georgetown, he acted as the Medical Director at the Vishnevskaya-Rostropovich Foundation, which created and managed health programs, including hepatitis B vaccine distribution for children in Russia and the newly independent states. 2 App. 355. Dr. Wientzen testified that he had examined approximately 10 to 12 Chronic Fatigue Syndrome patients per year over the past 30 years.

During his testimony, Dr. Wientzen changed his opinion from his pre-hearing written report. In his written report (which petitioners had a right to rely upon in preparation for trial), Dr. Wientzen rejected the claim that Ilya suffered from Chronic Fatigue Syndrome, but nevertheless opined that whatever he suffered from was caused by a virus. He did not identify that virus in his report. According to his written report:

In my opinion, if they hypothetically were a CFS to be diagnosed in Ilya, the precipitating event would have been not the vaccine he was given, but one of the two closely spaced viral illnesses that occurred between that night and the onset of vestibular neuritis on 11/30/01. [Last paragraph of Dr. Wientzen's Expert Report dated February 21, 2005] 2 App. 351

In his live testimony, he declared for the first time that if Ilya “hypothetically” did have CFS it came from the Epstein Barr Virus. When confronted with the fact that the petitioner’s mononucleosis was in the convalescent stage, he opined that, that was the case because the EBV had been masked because the petitioner’s mother had been giving him Acyclovir. Acyclovir had been prescribed to the mother in the emergency room visit on November 30, 2001, in connection with the episode of vestibular neuritis. 4 App. 161.

After the June 25 and 26, 2007, hearings, specific, additional documents were requested by the special master. Among these requested documents was a copy of Ilya's mother's diary along with a translation. 4 App. 39-43.

Because Dr. Wientzen had modified his testimony, petitioner filed a request with the special master for an opportunity to have Dr. Oleske offer rebuttal testimony which petitioner proffered would be contrary to Dr. Wientzen’s testimony that Acyclovir had no effect on EBV and would not be masking an active EBV. This meant that a convalescing EBV could not have been the cause of Ilya’s Chronic Fatigue Syndrome. This fact would make Dr. Wientzen’s opinion wrong as the petitioner's Chronic Fatigue Syndrome could not have been caused by the EBV as alleged by Dr. Wientzen.

This request was followed by a status conference on January 17, 2008, to discuss Petitioner's request to allow a hearing for rebuttal testimony by Dr. Oleske.



pleadings, (3 App 566, see medical articles at 3 App. 571 et seq.) Special Master Moran on April 7, 2009, entered an Order Denying a Supplemental hearing.

3 App. 556. On June 10, 2009, Petitioner filed a motion renewing his request for further consideration of the application of interim medical expert fees. 3 App. 623.

The special master, with full authority to order an interim payment would not exercise his authority. At a telephone status conference, he advised counsel that if the petitioner could reach an agreement with the government to allow an interim fee payment at a modified sum amount he would approve it and then allow petitioner to argue at the end of the case for a sum as requested by Dr. Oleske. The government, recognizing that it would not be to their adversarial advantage to allow Dr. Oleske the opportunity to rebut Dr. Wientzen's testimony, refused to agree to any payment. This was argued in opposing pleadings and thereafter the special master denied the request. 3 App. 622. The Government never acknowledged that there was anything wrong in their having presented a witness who had changed his testimony and instead blamed Petitioner's lawyers for not keeping their experts at the hearing. 1 App. 50.

The special master adopted the government's position even though the previous special master, who had seen the witnesses and had released Dr. Oleske from the hearing, had already ruled that a supplemental hearing should take place to allow the major conflict to be presented by both sides. In addition, even though

he had full authority to award interim fees, Special Master Moran, nevertheless, denied the request, made no reference to Dr. Wientzen's changed testimony, disregarded Special Master Edward's release of Dr. Oleske, and instead blamed petitioner's counsel for allowing Dr. Oleske to leave the hearing room before Dr. Wientzen had testified.

After denying allowance of an interim payment of a fee to Dr. Oleske, the special master made his 3/12/10 Decision Denying Entitlement 1 App. 49, stating:

Another issue is that petitioners permitted one witness whom they called, Dr. Oleske, to leave a hearing before its conclusion. His absence made him unavailable to rebut a particular point raised by a witness called by respondent—how a medication called acyclovir affected Ilya. 1 App 50.

The petitioner filed a Rule 24 Memorandum of Objections with the United States Court of Federal Claims.

After the United States Court of Federal Claims reviewed the record below and the special master's ruling the Court of Federal Claims issued its 7/30/10 Opinion and Order, 1 App 77 *et. seq.*, finding that the special master, for those reasons expressed in the order, had abused his discretion and, among other provisions, directed him to order the interim payment to Dr. Oleske and then to allow the requested rebuttal hearing.

## HEARING ON REMAND

Abiding the order, the special master scheduled a status conference in order to schedule a telephonic hearing for September 29, 2010, to hear additional testimony.

When the time was set, the government advised the special master that Dr. Brennen had died and Dr. Wientzen was travelling out of the country. Previously, when Special Master Edwards had set the “rebuttal hearing” he had learned that Dr. Brennen had died and offered an opportunity to the government to engage another expert, but they did not. So, in order to accommodate Dr. Wientzen who would not have returned from his travel on September 29, 2010, the special master set a second date of October 4, 2010, for an additional hearing for Dr. Wientzen’s testimony. 3 App. 724. This agreed accommodation would also give Dr. Wientzen an opportunity to review the testimony of Dr. Fink, Dr. Bell, and Dr. Oleske, and then to state his current position. In particular, with regard to his earlier testimony that he had doubted the diagnosis of Chronic Fatigue Syndrome without ruling out a psychiatric component, and that if the petitioner had indeed suffered Chronic Fatigue Syndrome it was from his EBV.

Considering the psychiatric report of from Dr. Charles Parker dated August 6, 2007, (2 App. 368-379) plus the passage of three years, by which time there was no question that the petitioner was suffering from Chronic Fatigue Syndrome, it

remained for the special master to determine the application of the requirements of the prongs of *Althen v. Sec'y of Health & Human Serv's* 418 F. 3d 1274 (Fed. Cir., 2005). The petitioner had the initial burden to prove the elements of *Althen*, which, if established, would shift the burden back to the government to prove the allegation made in the earlier testimony of Dr. Wientzen that the Chronic Fatigue Syndrome, if suffered by Ilya, would have been caused by the EBV.

Drs. Fink, Oleske, and Bell all appeared by telephone for the hearing on September 29, 2010. The stated purpose of the hearing was that the government's expert, Dr. Wientzen, offered in his first written report an opinion that Ilya did not have Chronic Fatigue Syndrome, but if he did then it came from some virus. While in his report Dr. Wientzen had not specified the virus, he did at the June 27, 2007, hearing, identify the virus as EBV. When he was confronted with the fact that the Polymerase Chain Reaction (PCR) testing had established that Ilya **did not** have an active Epstein Barr Viral infection at the time of the vaccination, Dr. Wientzen excused that test result by declaring that the EBV had been masked because Ilya had been taking Acyclovir medication. Subsequent testimony and exhibits established that Acyclovir had no effect on EBV. For that reason, it became incumbent upon the government to come forward with their expert, or some other expert, in order to meet their burden of proof of if it wished to establish

that the EBV and not the hepatitis B vaccine was the cause of Ilya's Chronic Fatigue Syndrome.

At the conclusion of the September 29, 2010, telephonic hearing, Dr. Oleske, Dr. Bell, and Dr. Fink were all asked if they would be available for a further telephone hearing on Oct. 4, 2010. 4 App. 191, 241. They all said they would make themselves available. The Government then, after a private conference, announced that they would not be calling Dr. Wientzen for further testimony. 4 App. 266. For the special master to ignore this requirement was an error of law. *Knudsen v Sec'y of Health and Human Servs.*, 35 F.3d 543, 549 (Fed. Cir., 1994).

It is a notable observation, not addressed by the government in its brief, that no explanation has been offered, as to why Dr. Wientzen was not produced. The special master in his decision issued on 10/27/10, Decision on Remand Denying Entitlement 1 App 96 *et. seq.* a mere 28 days later, made the following misleading statement:

Respondent did not call either of the two witnesses who had testified at the first hearing because both were not available. Dr. Brenner had died and *Dr. Wientzen was traveling outside the country*. 1 App 100, Para. 5. (Italics added)

The special master published this erroneous statement after having been clear on the record about the October 4, 2010, opportunity given to the government to



present Dr. Wientzen. He did not explain why he made this incorrect statement, but petitioner submits that in the context of this appellate proceeding this was an arbitrary and capricious act.

## STATEMENT OF THE FACTS

### EARLY HISTORY

Ilya Dobrydnev was born on April 14, 1991 in Moscow, Russia and was brought by his parents, Dr. Boris Dobrydnev, and his mother, Yuliya Dobrydneva, to Norfolk, Virginia. During 1992 and 1993, Ilya received three doses of the hepatitis B vaccine.

From October 1996 to October 2000, petitioner saw his pediatrician roughly 3 times a year for a variety of childhood illnesses, fever, sore throat, ear infections. He was academically advanced and participated in normal school activities.

4 App. 98-132

Late December 2000 or early January 2001, he became ill with mononucleosis, caused by an acute infection by the Epstein Barr virus (EBV). Once infected, the EBV does not go away, but becomes dormant or convalescent. During the period of his active mononucleosis, he had profound fatigue. 2 App 390; 1 App. 54-55, 78-79. During this time, petitioner had a series of periods of being tired, suffering from fever, and having white patches on his throat. On occasions, his fatigue was so pronounced on occasions that he had to be carried. 1 App 56, 79.

His acute mononucleosis was resolved by April, 2001, and he returned to a normal school routine. 4 App. 98 *et seq.* On April 23, 2001, he was taken to Dr.

Fink, whose diagnosis was sore throat, fever, and fatigue as a virus, but not mononucleosis. By May 2001, Dr. Fink concluded that Ilya was then cured of mononucleosis. 4 App. 303.

During the summer of 2001, Ilya attended a summer camp for academically gifted children where he played tennis and swam. 4 App. 110-111. Although on July 2, 2001, he did have some quickly resolved medical problems for which he was seen and examined by Dr. Fink and Dr. Cynthia Kelly. 2 App. 205, 407 et seq. he remained in good health.

In the fall of 2001, he began the fifth grade (4 App. 113) and was in good health and enjoyed a 4-day absence from school while traveling to Disney World with his parents. 4 App. 109-113.

### **VACCINATION AND THE CONSEQUENCES**

Life for Ilya was at its normal level and he was practicing for a tap dance competition, when on November 5, 2001, the school nurse administered a fourth vaccination of hepatitis B vaccine. He did not need this vaccination because he already had the required three, but the records were not clear or were incomplete. His grandmother took him to the school for the required vaccination. That evening, he reacted to the vaccination and began a fever. The next day he suffered malaise, fever, sore throat, swelling of the lymph nodes and marked pallor. He missed school on Nov 6 and 7 then returned to school when he began to feel better.

4 App. 117. When he was next taken to Dr. Fink's office on November 19, 2001, Dr. Fink diagnosed him as having "febrile illness/viral pharyngitis" 2 App. 204. Seven days later when petitioner suffered a yellow nasal discharge and a frontal headache, Dr. Fink made a diagnosis of sinusitis. Three days later he suffered a sore throat and finally on November 30 he suffered severe dizziness (vertigo) and nausea. This vertigo and nausea was so severe he had to be taken by ambulance to the emergency room at Children's Hospital where he was diagnosed with vestibular neuritis. 2 App. 203, 231. From the ER, he was released to return home. Thereafter, he continued school in a homebound program because he was too fatigued and weak to physically attend school.

After his November 30 hospital visit and diagnosis of vestibular neuritis, Ilya was seen by a series of doctors with various diagnoses.

In January, Dr. Jennifer Holland (Dr. Fink’s partner) saw Ilya. On his third visit on January 14, 2002, the doctor noted “recent [EBV] with possible recurrence versus exacerbation”. Three days later she had Ilya tested for EBV using a polymerase chain reaction (“PCR”) which did **not** detect the presence of the EBV.

4 App. 91.

With that result, Dr. Holland referred Ilya to Dr. Cynthia Kelly, an allergist/immunologist where he was seen on January 23, 2002, and February 19, 2002. During the second visit, Ilya's mother inquired if the hepatitis B vaccine

could be the cause of Ilya's medical problems. She did not get an answer. On the February 19, 2002, visit, the doctor noted that "... [Ilya] still fatigues easily and has been maintained on homebound [schooling]." 4 App. 39-43.

Dr. Holland also referred Ilya to Dr. Doug Mitchell an infectious disease specialist. Ilya was seen in two visits, February 19, 2002 and March 20, 2002. (Pet. Ex. 6 250-251, 268-270) The doctor reported that “the majority of [Ilya’s] symptoms are achy legs. He is very fatigued and tired” Dr. Mitchell was also questioning whether “there is a behavioral psychological component contributing to his continued subjective fatigue and possibly school avoidance.” 2 App. 384-385. Dr. Mitchell’s impression was that Ilya continued “to have subjective findings of fatigue.” There have been, in my repeated examinations and discussions, no objective findings to support evidence of infectious process.” Nevertheless, Dr. Mitchell also noted, “Chronic Fatigue Syndrome itself may be considered in this child.”

On April 1, 2002, Dr. Fink began to raise Chronic Fatigue Syndrome as a possible diagnosis.

Chronic Fatigue Syndrome is not a disease with an easy-to-diagnosis set of symptoms. The criteria for the diagnosis is a persistent debilitating fatigue lasting longer than six months with at least four of the following symptoms: significantly impaired short term memory or concentration, muscle weakness, pain in multiple

joints without swelling or redness, sore throat, tender lymph nodes, headaches, unrefreshing sleep, and malaise that lasts more than 24 hours following exertion.

*Dorland's Illustrated Medical Dictionary (31<sup>st</sup> Edition)* p. 185.

On May 6, 2002, Ilya had his tonsils and adenoids removed.

Throughout 2002, Ilya's mother and Dr. Fink continued to try to find a cure for Ilya. By December 16, 2002, Dr. Fink saw Ilya for what he termed "two years of symptoms that are best called Chronic Fatigue Syndrome.

Ilya continued suffering after November 30, 2001, with the on-going symptoms while he continued with homebound schooling provided by the Norfolk public school system (from time to time, when he was physically able, he would be returned to school for a short period). This is why he was marked present all that year even though he was physically at home where special teachers came to him.

On June 19, 2003, Ilya was taken to Dr. Randall G. Fisher, the medical director of Pediatric Infectious Diseases at Children's Hospital. 2 App. 169. 1 App. 78-83. In an unfortunate failure to appreciate the symptoms of Chronic Fatigue Syndrome, and in failing to understand the frustration and distress of the mother (exactly as the special master had failed) and in condemnation of her trying to find answers, the doctor declared that Ilya's mother bordered on Munchausen's syndrome-by-proxy or factitious disorder-by-proxy. Dr. Fisher then wrongly reported the frustrated and distraught mother to Child Protective Services.



approximately one and occasionally two hours of classes each day with special permission—due to his suffering from chronic fatigue syndrome—to record lectures, make up missed classes, and be granted extra time for exams in a "distraction-reduced setting." 4 App. 269-271.

Looking at this unfortunate young man as he is now, it is recognized by all that his Chronic Fatigue Syndrome has permanently crippled him. 4 App. 44.



## SUMMARY OF THE ARGUMENT

Petitioner established his entitlement to the recovery of an off-Table injury, Chronic Fatigue Syndrome, as a result of a hepatitis B vaccination he received on November 5, 2001. Chronic Fatigue Syndrome cannot be diagnosed until certain symptoms have been noted for a period of six months. In support of his claim, he met the requirements of the three “prongs” of *Alhen, supra* through the testimony of Dr. Bell and Dr. Oleske. Both doctors were experts in the field of Chronic Fatigue Syndrome and have been recognized and honored by the Department of Health & Human Services. Each doctor explained that the antigenic challenge to Ilya was the fourth, unnecessary hepatitis B vaccine which created a cytokine immunological cascade. This cascade did not shut down in a normal fashion but continued until it had caused the injury, Chronic Fatigue Syndrome.

The special master determined that the testimony delivered by Dr. Brenner and Dr. Wientzen, which challenged the diagnosis of Chronic Fatigue Syndrome, was more persuasive than that of the petitioner's experts. This judgment would normally control. However, the special master dismissed the testimony of the petitioner's mother, his mother's diary, the affidavit of the grandmother, and the testimony of Dr. Bell who actually performed a physical examination and took a history as a highly skilled pediatric specialist before offering assistance in the treatment of Ilya. The special master also did not acknowledge the statement by

the treating physician, Dr. Fink, who attributed Ilya's Chronic Fatigue Syndrome to the vaccine. In total, the United States Court of Federal Claims found that the special master had abused his discretion.

Dr. Wientzen, the government's expert, wrote a report that he doubted the diagnosis of Chronic Fatigue Syndrome and would not consider making a diagnosis until Ilya had a psychiatric evaluation to be sure he was not faking the symptom of fatigue. Although it must be noted that even after the psychological exam took place and confirmed that Ilya's suffering was genuine, Dr. Wientzen still refused to accept a diagnoses of Chronic Fatigue Syndrome. He had also previously asserted that if Ilya did have Chronic Fatigue Syndrome it was from an unknown virus.

At the first hearing, Dr. Wientzen changed his testimony by deviating from his written report and said that if Ilya did have Chronic Fatigue Syndrome it was from the Epstein Barr virus (EBV) from Ilya's earlier mononucleosis. However, when confronted with the fact that tests showed that the mononucleosis that Ilya had suffered earlier in the year was dormant, he claimed that it was really being masked by the use of medicine he was taking. Petitioner challenged that claim and asked for an opportunity to present Dr. Oleske's testimony to challenge Dr. Wientzen. The first special master agreed and set a hearing for Dr. Oleske and Dr. Wientzen to appear by telephone.

Before the hearing could take place, the first special master left the program and a second special master took over and after a series of motions, denied the new request and ruled that Ilya has not established the date of the onset of the injury.

The United States Court of Federal Claims reversed the special master, finding that the special master had been arbitrary and capricious in his ruling, and remanded the case for a further hearing.

The second hearing was scheduled. Dr. Fink, Dr. Oleske, Dr. Bell and Dr. Wientzen were scheduled to testify (Dr. Brenner having died). After a full and lengthy telephone hearing, the government elected not to call Dr. Wientzen. The special master then entered an order denying entitlement. In denying entitlement, the special master declared that Dr. Wientzen did not appear because he was travelling. This was false because the date for his appearance had been specially set to accommodate his travel schedule.

It was petitioner's argument that in his various rulings, the second special master had been arbitrary, capricious, abused his discretion, and had not correctly applied the law. The special master did not correctly apply the missing witness rule, nor the shift of the burden of proof to the government, nor the opinion of the treating physician (Dr. Fink), nor the requirement that when accepting certain evidence and rejecting other evidence within his right as the initial finder of fact was required to articulate plausible inferences, rational bases, or reasoned

explanations, particularly when he declined to draw inferences in favor of the petitioner for whom the law grants the benefit of close calls on causation.

*Capizzano v. Sec'y of Health & Human Services*, 440 F.3d 1317, 1327 (Fed. Cir., 2006)

Having detailed the errors of the special master, the United States Court of Federal Claims then set aside the findings and entered its own findings granting entitlement.

## STANDARD OF REVIEW

The appeal from the United States Court of Federal Claims in this Vaccine Act case is reviewed *de novo* by this United States Court of Claims for the Federal Circuit with no deference to the United States Court of Federal Claims or special master on questions of law, but with deference to the findings of fact by the special master unless those findings are arbitrary or capricious. *Porter v. Sec'y of Health & Human Servs.*, 663 F. 3d 1242 ( Fed. Cir., 2010).

When viewing the special master's procedural rulings as well as his factual determinations several key accepted standards should have been observed. "The Vaccine Act established a federal 'compensation program' under which awards are to be 'made to vaccine injured persons quickly, easily, and with a certainty and generosity" citations "The program is supposed to be 'fair, simple, and easy to administer." *Knudsen , supra*, 549 "...close calls regarding causation are resolved in favor of injured claimants. (citing *Knudsen*), *supra*." *Capizzano v. Sec'y of Health and Human Serv's*, 440 F.3d 1317 (Fed. Cir., 2006)

## ARGUMENT

Petitioner submits that *Capizzano, supra*, is on point with the instant case. That case involved a petitioner who suffered rheumatoid arthritis as a result of an hepatitis B vaccination. In *Capizzano*, the Special Master and the United States Court of Federal Claims denied her claim because her evidence showed the mechanism was more conceptual and theoretical than actual. In reversing both the United States Court of Federal Claims and the special master and remanding it for further findings, this Court ruled that the requirement under the statute as articulated by *Capizzano* is that:

...the 'preponderance of the evidence' standard referred to in the Vaccine Act as one of proof by a simple preponderance, of 'more probable than not' causation.' (citing *Hellebrand v Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed.Cir. 1993))). The fact that there is a possibility that the rheumatoid arthritis that appeared immediately after Ms. Capizzano received her vaccination was not caused by the vaccination does not prevent a finding that it is more likely than not that the vaccine caused the R.A. See *Althen III*, 418 F. 3d at 1280 ("[C]lose calls regarding causation are resolved in favor of injured claimants."). *Capizzano, supra*, 1327

Because this is an off-table case, it was the burden of the petitioner to establish the three elements of *Althen* to show by preponderant evidence that the hepatitis B vaccination brought about Ilya's Chronic Fatigue Syndrome by providing (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the

reason for the injury; and (3) a showing of a proximate, temporal relationship between vaccination and injury. It is the argument of petitioner that for all of the reasons articulated in both opinions from the United States Court of Federal Claims, petitioner has been successful. More importantly, even given deference to the special master's findings of fact, the ruling of the United States Court of Federal Claims should be affirmed because, the two rulings by the special master were arbitrary, capricious, an abuse of his discretion and not in accordance with law.

In support of his case, petitioner presented Dr. David Bell who had traveled to Norfolk and carefully examined Ilya. In rendering both of his opinions to deny entitlement, the special master neglected to mention the important distinction among the expert witnesses. The special master had to have decided that Dr. Bell's examination of Ilya, including the history he took of Ilya's illness, had no probative value, and that the combined testimony of Dr. Bell and Dr. Oleske, regardless of their impressive credentials and specialized knowledge of Chronic Fatigue Syndrome honored by the government itself by their medical appointments, was according to the special master, "less than supported" (1 App. 107) because of the "Canadian study" which study Dr. Oleske explained did not apply and the Court of Federal Claims agreed. 1 App. 136.

The special master in reaching his conclusions was required to examine all of the evidence and set out reasoned explanations for his rulings. Here he did not.

When the testimony of Dr. David Bell was reviewed by the special master, he failed to explain why no credibility was given to Dr. Bell's opinion based upon the fact that he was the only expert witness who actually, physically examined Ilya and who professionally took a history and interviewed the parents. In addition, Dr. Bell later responded to a request by Dr. Fink to assist in prescribing a treatment for Ilya. Dr. Bell's recommendations were detailed by Dr. Fink in his 2 page proposed medication in Dr. Fink's 8/2/04 chart. 4 App. 72. In assisting in the treatment of Ilya, Dr. Bell became more than an expert witness in the Vaccine Act medical hierarchy; he also became a treating physician. 4 App. 72.

Dr. Bell's opinion was that Ilya's Chronic Fatigue Syndrome was a dysfunction of the immune system responding to the hepatitis B vaccine stimulation by a sustained (normally an immune response is appropriate and shuts off when the antigen attack is over) inappropriate cytokine (interferon, interleukins) release as part of an immune response that does not shut. This results in fatigue, myalgia, and neurological short-term memory loss that form the basis for Chronic Fatigue Syndrome. Dr. Bell felt that the stimulus of the vaccination initiated encephalitis through an autoimmune response or sustained cytokine activity. This happened because Ilya had a predisposing, vulnerable condition



which was probably from his father as he had a primary immune deficiency disease. 4 App. 87. In short, Chronic Fatigue Syndrome, which cannot be diagnosed until the disturbing condition of the on-going occurrence of certain defined symptoms have lasted for six months. 4 App. 146, 224. The various doctors seen by Ilya in 2001 after the vaccination into 2002 were all struggling to find answers until the passage of time allowed the Chronic Fatigue Syndrome diagnosis to be made.

The petitioner also presented Dr. James Oleske, who expressed the same opinion that the principle of vaccinations was to stimulate the immune system by simulating as much as possible the natural consequence of infection without giving the person the disease. He continued, stating that the hepatitis B vaccine contained adjuvants or immune stimulants to make the vaccines effective enough to develop antibodies and cell mediated immune responses. Dr. Oleske tied the onset of Ilya's Chronic Fatigue Syndrome to the hepatitis B vaccination as "an unusual but known complication of hepatitis B vaccination." He further explained, "It results in the cascade of inflammatory mediators [called] cytokines." 4 App. 304-315.

The special master disregarded the testimony of petitioner's two expert witnesses and rejected the petitioner's claim because none of petitioner's treating physicians identified Ilya's hepatitis B vaccinations as the cause of Ilya's Chronic Fatigue Syndrome.

In making his ruling he entirely ignored the brief role served by Dr. Bell is assisting Dr. Fink in a treatment regimen, evidence that should have been addressed by the special master.

A more significant matter: In a July 29, 2005, letter addressed to the United States Court of Federal Claims, Dr. Robert Fink, Ilya's pediatrician, explained that since Ilya's hepatitis B vaccination on November 5, 2001, Ilya had been ill, and that as his doctor, he had sought many consultants trying to diagnose the cause of his illness disease and hopefully be able to perfect a cure. As Dr. Fink wrote:

It is my belief that this child does in fact have Chronic Fatigue Syndrome and since I am not an expert in this field, I deferred to the opinions of Dr. David Bell whom I met when he came to Norfolk to examine this child. We discussed Ilya thoroughly at that time and since then Dr. Bell has been in touch with me regarding further management of Ilya's Chronic Fatigue Syndrome. Dr. Bell is a well-known, highly regarded, and published author on childhood CFS. *I agree with Dr. Bell's expert opinion that Ilya has Chronic Fatigue Syndrome, he will likely not recover from it, and it was precipitated by the vaccination with Hepatitis B vaccine.* 2 App 366-367. (emphasis provided)

In making his ruling, the special master failed to include the fact that Dr. Fink, the primary treating physician had made that declaration. The special master also failed to give any consideration to the fact that Dr. Fink had filed a VAERS Report on May 6, 2004, identifying Ilya's hepatitis B vaccination with vestibular neuritis and Chronic Fatigue Syndrome. 2 App. 430.

It was the special master's obligation to consider all of the relevant evidence, and then provide reasoned explanations when he rejected evidence. The special master did not do this; he simply did not mention some significant items of evidence. This omission without explanation was arbitrary and capricious.

When Dr. Wientzen was asked about the VAERS Report he stated:

“I have not seen the VAERS [R]eport. I don’t know if that’s considered evidence or not, but that one thing I would love to review. I have not seen it.” 4 App. 316.

Dr. Wientzen did not testify as to whether that report would have changed his view of the case. However, he was given the opportunity to express his view at the hearing scheduled for October 4, 2010, but he did not—or at least the government did not elect to present him before the special master again. In his second ruling on October 27, 2010, the special master failed to address the VAERS Report to the CDC by Dr. Fink, or to discuss Dr. Wientzen's failure to use his October opportunity to discuss its importance or unimportance in this case. 1 App. 96-114. As stated above, the special master did worse: he declared that Dr. Wientzen was not available when the special master had to have known that not to be the fact. This failure was arbitrary and capricious. 1 App. 100.

Also, a legal principle that the special master should have addressed was the application of the missing witness rule, the evidentiary presumption that Dr.

Wientzen's October 4, 2010, testimony would have been harmful to the government's adversary position:

[I]f [a] party chooses to not call [witnesses within his control to produce], the fact finder *may* draw the inference that the testimony would be unfavorable. (emphasis added)

*White Buffalo Construction, Inc. v United States* 490 F 3d 934, 939 (Fed. Cir., 2007).<sup>1</sup>

While "may" makes the application of this rule optional, a judgment call, it is the petitioner's position that it was, at the very least, the duty of the special master to recognize the legal principle and articulate a plausible inference, rational basis, or a reasoned explanation as to why he, as the fact finder, declined to draw that inference in favor of the petitioner for whom the law grants the benefit of close calls on causation (*Capizzano v. Sec'y of Health and Human Serv's*, 440 F.3d 1317, 1327 (Fed. Cir., 2006)). The answer given by the special master was that Dr. Wientzen "was not available because he was travelling." 1 App. 100. This misleading statement intended to excuse Dr. Wientzen for not being present on October 4, 2010, was an abuse of the special master's discretion and a capricious act.

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<sup>1</sup> Dr. Wientzen would be considered an expert who would be within the control of the government because he has been an expert witness for the government in Vaccine cases for 15 years including 10-12 actual trials prior to the 2007 hearing. 4 App. 318-319

Then there is the matter of burden of proof. If petitioner is able to establish causation in fact, then the burden of proof shifted to the government to establish that a factor unrelated to the vaccination was the actual cause of the petitioner's injury. 42 U.S.C. § 300aa-13(a)(1)(B), see also *Pafford vs. Sec'y of Health and Human Serv's* 451 Fed. 3d 1356, 1365 (Fed Cir., 2006). Dr. Wientzen had testified that if Ilya had suffered Chronic Fatigue Syndrome (which he doubted) then it would have resulted from the EBV. That being the government's position, then Dr. Wientzen needed to attend the October 4, 2010, hearing in order to give testimony in support of this position. He did not. The answer given by the special master was, as previously addressed, that Dr. Wientzen "was not available because he was traveling." This misleading statement intended to excuse Dr. Wientzen for not being present on October 4, 2010, was an abuse of the special master's discretion, a capricious act, and a failure to correctly apply the law.

It is petitioner's argument that the special master revealed throughout the proceedings that he did not want to approve Ilya's petition. In his first ruling, he obviously understood that petitioner had provided a persuasive medical theory which was advanced by highly recognized expert medical testimony causally connecting the vaccination and the injury and by proof of a logical sequence connecting the vaccination to the injury or at least casting the vaccination as a substantial factor in bringing about the injury. It is here posited that for this reason, the special master at the conclusion of the first trial declared that he did not

need to address prong one or two of the three prongs of *Althen* because he had ruled that petitioner's mother's testimony was not reliable, and by eliminating reliance on her testimony about the immediate fever and reaction suffered by Ilya on the evening of the vaccination, he could declare that there was no evidence that the reaction began on November 5, 2001, thus not supporting the temporal opinions of Dr. Bell and Dr. Oleske.

This, he reasoned, eliminated a date of onset and thus a nexus between the vaccination and the Chronic Fatigue Syndrome that Ilya "might" have suffered. However, in order to eliminate other evidence of the immediate onset he also had to deal with the mother's diary and the grandmother's recollection.

To declare that, in his opinion, the mother's testimony was unreliable would arguably be within his right as the fact-finder. However, he extended his rejection of her testimony to her diary. The entries in the diary about that evening as well as the following few days were contemporaneous records and could hardly be in contemplation of litigation. Her child had a hepatitis B vaccination and had an immediate reaction. She noted the fact. He was out of school for a few days, then was better, and returned to school. That was in the diary. A child with a temporary reaction to a vaccine would not be a remarkable event since he got better, or at least then appeared to be well enough to go to school. Since he appeared better there would be no rush to the doctor. The special master ignored the evidence provided in the diary by cloaking it in the rejection of the mother's

testimony. He dismissed the missing school days by declaring the entry as meaningless because the diary did not specify why he missed school. This dismissive remark is ill placed considering the diary entry of his illness. The special master could not challenge the entry in any other manner because his absence from school was verified by school records. ( See 5/10/04 report from Dr. Judy McClary 4 App. 318-320). Instead, he criticized the mother's actions because she did not take him to the doctor on 11/6/01 occasion.

Since her diary was made at the time of the events and long before any litigation was in contemplation, the special master did not offer a reasoned explanation for disregarding that item of proof, which corroborated the moment of the onset of the initiating antigenic event. The vaccination event, followed by the symptoms leading up to the vestibular neuritis, and thereafter along the torturous path to Chronic Fatigue Syndrome identified the precise moment of "proximal temporal relationship."

In a similar fashion, the special master ignored the affidavit from the grandmother. 4 App. 17. No explanation was offered. If the Special Master considered the grandmother's sworn statement to be false, he was obliged to say so and offer a reasoned explanation. He did not. If he ignored the grandmother's affidavit because he found the mother's testimony unreliable, did that include the grandmother? He made no mention of that oversight.

While it is true that credibility of experts who have been seen and heard by a special master is uniquely unchallengeable on appeal, the circumstances in this case are different. The special master did not see nor hear the expert witnesses in 2007. 1 App. 93. On the other hand, in 2010, he did hear the petitioner's experts, Dr. Bell and Dr. Oleske, when they testified at length with questioning directly from the special master. The credentials of each are extensive in the field of Chronic Fatigue Syndrome as each were uniquely recognized by the government, as previously provided in detail, as Chairmen of the Chronic Fatigue Syndrome Advisory Committee to the Department of Health and Human Services. 1 App. 84.

As articulated in *Cappizzano, supra*, 1320:

The Vaccine Act provides that the Court of Federal Claims has jurisdiction to review the record of the proceedings before the special master and that, following such review, the court may: (A) uphold the findings of fact and conclusion of law of the special master and sustain the special master's decision, (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance of law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

In this case the Court of Federal Claims did remand the matter for further action. The remanded action by the special master was again arbitrary and an abuse of discretion. The Court of Federal Claims for the second time correctly set aside the findings of fact and conclusions of law and issued its own findings of fact and conclusions of law.



## CONCLUSION

For the foregoing reasons, this Court should affirm the judgment of the United States Court of Federal Claims and affirm the subsequent underlying determinations that the petitioner is entitled to the awarded compensation under the Vaccine Act.

Respectfully submitted,

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January 27, 2014

**United States Court of Appeals  
for the Federal Circuit**  
*FRIEDLANDER-DOBRYDNEV v HHS, 2013-5118*

**CERTIFICATE OF SERVICE**

I, Robyn Cocho, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by FRIEDLANDER, FRIEDLANDER & EARMAN PC, Attorneys for Appellee, to print this document. I am an employee of Counsel Press.

On **January 27, 2014** counsel for Appellant has authorized me to electronically file the foregoing **Brief for Appellee** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users, including any of the following:

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Paper copies of the brief will be mailed upon courts approval.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

January 27, 2014

/s/ Robyn Cocho  
Counsel Press

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I hereby certify pursuant to Fed. R. App. 32(a)(7)(C) that the foregoing brief was printed using a 14 point proportional Times New Roman font and contains 9,747 words, according to the count of Microsoft Word.

January 27, 2014

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